that analysis. Had it done so, it would have been forced to conclude that a judgment against PM USA based on application of the "consumer expectations test" effectively imposes on PM USA a duty to provide California consumers with additional warnings regarding health hazards associated with smoking Marlboro Lights. PM USA is forced to provide these warnings because if it wishes to continue to market Marlboro Lights in California, it must do something to bring consumer expectations regarding the safety of its product (which the jury deemed to be too high) into line with the priduct's actual safety level. The Labeling Act bars California from imposing any such duty. Review is warranted to correct that error, which threatens to undermine Congress's efforts to establish uniform cigarette labeling and advertising requirements throughout the country.

I. REVIEW IS WARRANTED TO PRESERVE THE UNIFORMITY PRINCIPLE THAT ANIMATES THE LABELING ACT AND SIMILAR FEDERAL STATUTES

In a wide variety of contexts, Congress has adopted legislation designed to protect consumers by mandating that businesses provide safety warnings regarding their goods and services – and also designed to ensure that business do not face a mishmash of nonuniform warning requirements from State regulators. The Labeling Act is one such statute. Review is warranted because of the importance to the business community of that uniformity principle and because the decision below threatens to undermine enforcement of that principle in the context not only of tobacco regulation but in other regulatory contexts as well.

By adopting the Labeling Act, Congress sought to ensure that the public would be "adequately informed" about the health risks associated with smoking by requiring every cigarette

package (and, later, by requiring every cigarette advertisement) to carry health warnings specified by Congress itself. At the same time, Congress also sought to "protect commerce and the national economy" to "the maximum extent consistent with [that] declared policy" by preserving the cigarette manufacturers' ability to advertise and label their products free from "diverse, nonuniform, and confusing" state and local regulations based on smoking and health. 15 U.S.C. § 1331.[2]

To give effect to this policy of national uniformity – protecting cigarette advertising and labeling while providing for the dissemination of government warnings about smoking – the Labeling Act contains an explicit preemption provision that provides:

---

[2] Section 1331, which declares the policy and purpose of the Federal Cigarette Labeling and Advertising Act, provides in its current form:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby--
>
> > (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
> >
> > (2) commerce and the nation economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331.

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. § 1334(b). The Labeling Act further provides, "No statement relating to smoking and health, other than the statement required by [15 U.S.C. § 1333], shall be required on any cigarette package." 15 U.S.C. § 1334(a).

As the Court has noted, Congress passed the current form of the Labeling Act preemption provision in 1969, in the face of efforts at the state level to regulate and even ban cigarette advertising. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 515 & n.11 (1992) ("For example, the California State Senate passed a total ban on both print and electronic cigarette advertisements."). The Court has observed that, when Congress amended the Act in 1969-70, it substantially broadened the pre-emption provision. *See id.* at 520 ("Compared to its predecessor in the 1965 Act, the plain language of the 1969 Act is much broader."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542 (2001) ("Without question, the second clause is more expansive than the first; it employs far more sweeping language to describe the state action that is pre-empted."). Prior to the 1969 amendment, § 1334(b) had merely precluded state and local authorities from requiring any "statement relating to smoking and health . . . in the advertising of any cigarettes." As amended, the expansive language of the preemption provision does much more than prohibit state and local regulation of the content of cigarette advertising; it now precludes any state or local authority from passing "requirement[s] or prohibition[s] based on smoking and health . . . with respect to the advertising or promotion" of cigarettes. 15 U.S.C. § 1334(b).

Cipollone made clear that Labeling Act preemption applies to requirements/prohibitions imposed by the common law as well as by statutes and regulations:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we stated in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief."

Cipollone, 505 U.S. at 521 (plurality) (quoting *San Diego Building Trades Council v. Gammon*, 359 U.S. 236, 247 (1959)); *see id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part).

The decision below has imposed on PM USA a common-law duty, if it wishes to continue to market Marlboro Lights in California, to eliminate any expectation among consumers in the State that smoking Marlboro Lights is less hazardous. It is difficult to conceive how PM USA can ensure that California juries will not continue to conclude that consumers have unrealistically high safety expectations for Marlboro Lights, other than by including additional health warnings in its labeling and advertising directed to Californians. But by requiring PM USA to provide such additional health warnings in order to allow it to continue to market its legal product in the State, California undercuts the uniformity principle animating the Labeling Act. By requiring additional health warnings within the State, California is potentially "imped[ing]" "commerce and the national economy" by imposing "diverse, nonuniform and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." 15

U.S.C. § 1331(2). Review is warranted to determine whether Congress intended to permit States to undermine the uniformity principle in this manner.

Other federal regulatory statutes contain preemption provisions that are designed to ensure national uniformity in regulation and are similarly threatened by the decision below. For example, in order to ensure nationwide uniformity in the regulation of medical devices, Congress broadly prohibited States from imposing "any requirement" on a medical device "which is different from, or in addition to, any requirement" imposed on the device by the federal Medical Device Amendments of 1976, and "which relates to the safety and effectiveness of the device." 21 U.S.C. § 360k(a). This preemption provision is fully applicable to State "requirements" imposed by the common law. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Although § 360k(a) is generally understood to preempt common-law suits based on claims that the product label failed to include warnings not mandated by the federal Food and Drug Administration, the decision below suggests that § 360k(a) might not preempt product liability claims based on a "consumer expectations test" – thereby paving the way for non-uniform labeling requirements in States permitting such claims.

Similarly, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, imposes strict labeling requirements on pesticides and at the same time ensures national uniformity in requirements by providing that States "shall not impose or continue in effect any requirementr for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). The Court has construed this provision as preempting any common-law failure-to-warn claims to the extent that such claims effectively impose labeling requirements that are "in addition to or different

from" those required by FIFRA. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005). The decision below jeopardizes that uniformity provision by suggesting that product liability claims against a pesticide manufacturer based on a "consumer expectations test" might not be preempted by § 136v(b).

Federal preemption provisions that govern regulation of service providers may be similarly affected. For example, the Federal Railroad Safety Act of 1970 (FRSA), 84 Stat. 971 (1970), 45 U.S.C. § 20101 *et seq.*, regulates the types of warning devices that railroads must install at railroad crossings. When warning devices are installed using federal funds and in conformity with regulations adopted pursuant to the FRSA, the statute preempts common-law failure-to-warn actions challenging the adequacy of those warning devices. *Norfolk Southern Railway Co. v. Shanklin*, 529 U.S. 344 (2000). The decision below suggests that other common-law actions might not be preempted even if they would have the effect of creating warning requirements in addition to those mandated by FRSA regulations.

Similarly, the Airline Deregulation Act of 1978 ("ADA"), 92 Stat. 1705 (1978), mandates a uniform national policy of deregulating the airline industry by preempting virtually all State regulations relating to "rates, routes, or services." 49 U.S.C. § 41713(b)(1). Thus, the Court ruled in *Morales v. TWA*, 504 U.S. 374, 383 (1992), that the ADA "express[ed] a broad preemptive purpose" and that States were not free to regulate advertising regarding airfares. More recently, lower federal courts have ruled that the ADA and the Federal Aviation Act ("FAA") preempt State common-law failure-to-warn claims that airlines should warn passengers on every flight that they should walk about the cabin to avoid developing deep vein thrombosis. *Witty v. Delta Air Lines, Inc.*, 366 F.3d 380 (5th Cir. 2004); *In re Deep Vein Thrombosis Litigation*, 2005 U.S.

Dist. LEXIS 4043 (N.D. Cal. 2005). As the judge hearing the latter case (a multi-district proceeding) explained:

> [S]tate-law suits based upon a failure to warn of DVT would most certainly lead to non-uniformity (anathema to the FAA), for each time a state jury sustains a failure to warn challenge, airline defendants would be forced to amend their pre-flight warnings to avoid future liability. Moreover, such state law verdicts could be inconsistent among themselves.

Id. at *44. The decision below suggests that while failure-to-warn claims against airlines may be preempted by the ADA and FAA, other common-law claims might not be preempted even if they have the effect of imposing on airlines a duty to provide additional health warnings to their passengers.

In sum, the decision below potentially affects a broad range of businesses that currently enjoy federal statutory protection against nonuniform State regulations. Review is warranted in light of the potentially broad impact of the decision below on this uniformity principle.

II. REVIEW IS WARRANTED BECAUSE THE ISSUE RAISED HERE RECURS FREQUENTLY AND HAS DIVIDED THE LOWER COURTS

Review is also warranted because the lower courts are deeply divided over whether a product liability claim based on the "consumer expectations test" is preempted by federal law whenever an equivalent failure-to-warn claim is preempted. Because at least 25 of the 50 States apply some form of the "consumer expectations test" to product liability claims, this issue has arisen often in the past and can be expected to arise

with regularity in the future. The Court should grant review to resolve this conflict.

Use of the "consumer expectations test" in strict product liability claims generally derives from Comment i of § 402A of the RESTATEMENT (SECOND) OF TORTS (1965), which provides the following definition of an "unreasonably dangerous" product:

> The article sold must be dangerous to an extent beyond which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.

In the years following 1965, the great majority of States adopted some variant of this definition, which came to be known as the "consumer expectations test." In 1978, in the course of adopting much of § 402A, the California Supreme Court held:

> [A] product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) in light of the relevant factors [discussed more fully in the opinion], the benefits of the challenged design do not outweigh the risk of danger inherent in the design.

Barker v. Lull Engineering Co., 20 Cal. 3d 413, 418 (1978).[3]

---

[3] The second of the two methods outlined by *Barker* for establishing a design defect – generally referred to as a risk-utility analysis – is not at issue in this case. The sole basis upon which the Court of Appeal upheld the product liability award in this case was use of the "consumer expectation test" – the first of the two methods outlined by *Barker*. Pet. App. 28a.

Just how juries should go about determining how safely an ordinary consumer would expect a product to perform has been a matter of considerable controversy in the ensuing decades. Some commentators have concluded that the only way to determine what consumers should reasonably expect from a product is to assess the product's risks and benefits in light of potential alternative designs. Because that formulation sounds remarkably similar to a risk-utility analysis, the drafters of the Restatement (Third) of Torts have suggested doing away with the "consumer expectations test" as a separate basis for recovery in a product liability action. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, Reporters Note, cmt. d (1998).

Nonetheless, a large number of States adhere to the "consumer expectations test." One recent survey of state tort law placed the number of such States at 25. *See* John F. Vargo, "The Emperor's New Clothes: The American Law Institute Adorns a 'New Cloth' for Section 402A Products Liability Design Defects – A Survey of the States Reveals a Different Weave," 26 U. MEM. L.REV. 493, 951 (1996). *See also McCathern v. Toyota Motor Corp.*, 160 Ore. App. 201, 208 n.5 (1999) (listing cases from numerous States adopting the "consumer expectations test"). As the decision below indicates, California is one of those States.[4]

---

[4] More recent California Supreme Court decisions indicate that a manufacturer may be held liable under the "consumer expectations test" only if the product has a relatively simple design. If the product is more complex, the court concludes that the ordinary consumer is incapable of determining whether the product is as safe as it should be; in such cases, expert testimony is required regarding risk-utility analysis and whether alternative designs would render the product safer. *Soule v. General Motors Corp.*, 8 Cal. 4th 548 (1994).

Given the widespread acceptance of the "consumer expectations test" as one method of establishing a product liability claim, it is hardly surprising that the issue presented in this case arises frequently: are product liability claims proceeding under the "consumer expectations test" preempted by federal law when analogous failure-to-warn claims are preempted? If, as here, a product liability claim does not proceed on the basis of a risk-utility analysis, then determining consumer expectations requires, of necessity, an examination of statements a manufacturer has made regarding its product. The more health and safety warnings a manufacturer has made regarding its product, the less viable is a claim that a product failed to perform as safely as an ordinary consumer would expect. Accordingly, if federal law preempts a failure-to-warn claim, there is reason to conclude that the same federal statute may preempt a product liability claim proceeding under the "consumer expectations test," since the latter claim presupposes that the manufacturer allowed consumer expectations to rise too high by failing to give sufficient warnings regarding health and safety risks.

As the Petition well documents, federal and State courts are irrevocably divided over this issue. WLF will not repeat here all the relevant cases cited in the Petition. It bears repeating, however, that California state and federal courts are on opposite sides of this issue. The Ninth Circuit held in *Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997), a product liability claim proceeding under the "consumer expectations test" against a medical device manufacturer, that the claim failed as a matter of law because the manufacturer had complied fully with all federally mandated warning requirements. 107 F.3d at 743 ("To rule otherwise would allow the anomalous circumstance that a consumer is entitled to expect a product to perform more safely than its government-mandated warnings indicate."). Four years later,

the California Court of Appeal explicitly declined to follow *Papike* in a FIFRA case. The court ruled that even though 7 U.S.C. § 135v(b) preempted the plaintiffs' failure-to-warn claim against pesticide manufacturers and distributors, it did *not* preempt the plaintiffs' product liability claim proceeding under the "consumer expectations test." *Arnold v. Dow Chemical Co.*, 91 Cal. App. 4th 698, 716-717 (2001). The court below relied on *Arnold* in concluding that Respondent's product liability claim was not preempted by the Labeling Act.

As PM USA notes, granting review to resolve a conflict among the lower court is particularly appropriate when the conflicting decisions are from federal and state courts within the same State. Pet. 10 (citing *Baldwin v. Alabama*, 472 U.S. 372, 374 (1985)). Unless that conflict is resolved, whether a California product liability claim proceeding under the "consumer expectations test" is preempted by federal law will often depend entirely on whether a defendant is successful in removing the case from state to federal court.

In sum, the preemption issue raised by the Petition is one that has deeply divided state and federal courts. That conflict will remain and will arise with regularity unless the Court grants review to resolve the conflict.

III. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH THIS COURT'S PREEMPTION DECISIONS

Review is also warranted because the decision below is so clearly at odds with the decisions of this Court that have addressed federal preemption claims. The California Court of Appeal's rationale for rejecting PM USA's preemption claim amounted to little more than an assertion that Respondent's product liability claim proceeding under the "consumer

expectations test" was a distinct cause of action from a failure-to-warn claim (which the court apparently conceded *was* preempted under the Labeling Act). Pet. App. 29a.

That California law deems Respondent's product liability claim as one distinct from a failure-to-warn claim simply misses the thrust of preemption analysis under the Labeling Act. The Court has made clear that whether a common-law claim is preempted by federal law does not depend on the name assigned to that claim:

> [Distinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would "elevate form over substance and allow parties to evade" the preemptive scope [of federal law] simply "by relabeling their contract claims as claims for tortious breach of contract."

Aetna Health Inc. v. Davila, 542 U.S. 200, 214 (2004) (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 211 (1985)).[5]

Rather, the question that must be answered is one that the California Court of Appeal never addressed: does the common-law duty imposed on PM USA as a result of the judgment below amount to a "requirement or prohibition based on smoking and health" imposed "with respect to the advertising or promotion of any cigarettes," 15 U.S.C. § 1334(b), or a "statement relating to smoking and health . . . required on any cigarette package"? 15 U.S.C. § 1334(a). As the Court explained in *Cipollone*:

---

[5] In *Aetna Health*, the Court ruled unanimously that the plaintiffs' causes of action were preempted by the preemption provisions of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1001. The Court deemed it irrelevant, for purposes of deciding the preemption issue, that the plaintiffs had characterized their action as one sounding in tort rather than contract. *Id.*

> The central inquiry in each case is straightforward: we ask whether the legal duty that is the predicate of the common-law damages action constitutes a "requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion," giving that clause a fair but narrow reading.

Cipollone, 505 U.S. at 523-24 (plurality). *See also Bates*, 125 S. Ct. at 1799 ("The proper inquiry calls for an examination of the elements of the common law duty at issue.").

The common-law duty imposed on PM USA as a result of the judgment in this case is relatively clear: if it wishes to continue to market Marlboro Lights in California, it must do something to bring consumer expectations regarding the safety of its product (which the jury deemed to be too high) into line with the product's actual safety level. PM USA is, of course, already doing quite a bit to lower consumer expectations of safety: every Marlboro Lights package label and every advertisement for Marlboro Lights contains one of the strong health warning mandated by the federal government. If, as Respondent contends, consumers continue to believe that "light" cigarettes (*i.e.*, those for which less tar is inhaled when smoked in the same way as ordinary cigarettes) are significantly safer than ordinary cigarettes, then PM USA's only means by which it can reduce consumer expectations is to include additional health warnings on its package labels, advertisements, and other promotional materials.[6] Certainly, neither Respondent nor the Court of Appeal suggested an

---

[6] Not even the Court of Appeal contends that making Marlboro Lights significantly safer is a viable means of bringing product safety into line with consumer expectations. The Court of Appeal quoted one expert witness as testifying that "the only way to reduce the risk is to quit smoking." Pet. App. 29a n.16.

alternative means by which PM USA could lower consumer expectations.

Accordingly, the common-law duty imposed on PM USA by virtue of this lawsuit is preempted by the Labeling Act; that duty consists of a requirement that it provide additional health warnings on its package labels and advertisements. Such a requirement is preempted by 15 U.S.C. § 1334(a) and (b).

In an effort to distinguish between Respondent's product liability claim and a failure-to-warn cause of action, the Court of Appeal asserted: "Since smokers do not know they compensate, a warning may not make the product any safer." Pet. App. 29a. That assertion illustrates the Court of Appeal's fundamental misunderstanding of the preemption issue raised by the Labeling Act. Whether one is asserting a failure-to-warn cause of action or a product liability cause of action that is proceeding under the "consumer expectations test," the point of a warning requirement is not to make the product safer, but rather to alert the consumer that the product is not as safe as he or she might otherwise believe. Imposing a common-law requirement on cigarette manufacturers that they provide additional health warnings on California packaging and advertisements (*e.g.*, "WARNING: Due to the tendency of smokers to 'compensate' by drawing more smoke into their lungs, Marlboro Lights are no safer than ordinary cigarettes and in some instances may be more dangerous") would undoubtedly serve to lower consumer health expectations regarding light cigarettes and thereby bring PM USA into compliance with the duties imposed under California product liability law. But any such requirement is a clear violation of the Labeling Act, which prohibits States from imposing any "requirement . . . based on smoking and health . . . with respect to the advertising and promotion" of cigarettes, 15 U.S.C. § 1334(b), or requiring that any "statement relating to smoking and health" be placed on the

cigarette package, 15 U.S.C. § 1334(a), and would undermine the national uniformity principle embodied in the Labeling Act.

In sum, review is also warranted because the decision below is in clear conflict with the decisions of this Court.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

Dated: December 22, 2005